

Appl. No. 09/995,277

Response Dated November 12, 2003

Reply to Office Action of August 18, 2003 (Paper No. 13)

REMARKS/ARGUMENTS

The above-identified patent application has been reviewed in light of the Examiner's Action mailed 18 August 2003 (Paper No. 13). Claims 108-111, 113, 116, 122-134, 136-140, 142 and 146 are pending. As set forth more fully below, reconsideration and withdrawal of the Examiner's rejections of the claims are respectfully requested.

Claim Rejections Under 35 U.S.C. § 103

The Examiner has maintained the previous rejection of Claims 108-111, 113 and 116 under 35 U.S.C. § 103(a) and has extended this rejection to include Claims 129 and 131. The Examiner rejects these claims as being obvious over U.S. Patent No. 5,932,575 (hereinafter "Yanaka"). The Examiner argues that the compound of the instant claim 116 is taught by the compound and the accompanying definitions of Chemical Formula 3 (General formula I described at col. 3, line 10 through col. 4, line 20) with the exception of the position of the carboxylic substituent on the phenyl group of Yanaka's R⁵. The Examiner argues that it would have been obvious to synthesize the compound of pending Claim 116 in view of Yanaka's disclosure because "it would have been reasonable to expect the three position isomers of such close structural similarity to exhibit the same pharmacologic activity."

First, Applicants note that R¹³ of Yanaka's Chemical Formula 3 (General formula I) is defined to be a "hydrogen atom, an alkyl group having 1-6 carbon atoms, a haloalkyl group having 1-6 carbon atoms, -NHC(=O)(CH₂)_mC₆H₅, -NHC(=O)R²⁹, -NHC(=O)CH(C₆H₅)₂, -NH₂, -NHR³⁰, or -(CH₂)_nC₆H₅" (col. 3, lines 47-51) and therefore excludes the carboxylic acid moiety of the compound of pending Claim 116. Thus, without reference to the Examiner's arguments about the R⁵ moiety, the compound of pending Claim 116 falls outside the definition of Yanaka.

Second, Applicants note that contrary to the Examiner's argument that "it would have been reasonable to expect the three position isomers" to "exhibit the same pharmacological activity," Yanaka does not disclose any such 3-position isomers. Yet Yanaka does disclose numerous different compounds, all of which have different substituents at the 4-position. As shown in Table I and described in Examples 1-3, Yanaka discloses 14 compounds falling within the definition of General formula I. Each of these compounds has a phenyl group in the R¹² position and each one of these phenyl groups is only substituted at the 4-position (in compound 11, the phenyl group is substituted at the 4-position with another phenyl group substituted at the 2-position).

Further, Yanaka discloses U.S. Patent Nos. 5,128,355; 5,153,197; and 5,155,118 having imidazole derivatives and EP Patent No. 0475206 having benzene derivatives as prior art in the background section of the patent. Each of these references teach angiotensin II receptor antagonists having a corresponding phenyl group that is only substituted at the 4-position. Thus, it is apparent that those of skill in the art that are synthesizing and testing angiotensin II receptor compounds do not consider it reasonable to synthesize compounds having a phenyl group substituted at the 3-position as R⁵ of Yanaka's General Formula I. For these reasons, Applicants submit that presently pending Claims 108-111, 113, 129 and 131, and specifically the compound of Claim 116, are not rendered obvious by the disclosure of Yanaka.

Additionally, the Examiner argues that Applicant's previous arguments regarding Yanaka are directed to the intended use of Yanaka's compounds and the compounds of the present invention and that the intended use of the compounds confers no patentable weight to composition claims. Applicants agree that the intended use of these compounds does not

distinguish the composition claims of the present invention over the compounds disclosed by Yanaka. However, Applicants previous arguments were directed to the motivation to modify the compounds of Yanaka to form compounds of the present invention. Specifically, as the Examiner states, and as explained in greater detail above, the compounds of Yanaka do not anticipate the compounds of the present invention, but must be modified with a carboxyl group at R⁵ and a carboxylic acid at R¹³. Thus, the Examiner rejects the claims as obvious over Yanaka. However, to establish a *prima facie* case of obviousness, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Applicants submit that this requirement of the *prima facie* case of obviousness is lacking in the Examiner's obviousness rejection over Yanaka. Specifically, Applicants submit that there is no motivation for one of skill in the art to begin with a compound that Yanaka teaches is effective in the inhibition of AT2 receptors and modify the compound with a carboxyl group at R⁵ and a carboxylic acid at R¹³ in an attempt to synthesize compounds that bind in the putative binding site of an antibody Fc region. This is the reason for Applicants' previous comments in regard to the intended use of the compounds: not that Applicants believe that the intended use confers patentability to the composition claims but that there is no motivation for one of skill in the art to take compounds effective for one purpose and modify their substituents in an attempt to isolate suitable matches for the binding site of unrelated biological molecules.

The Examiner also states that the Applicants' recitation of "vasculitities" encompasses various diseases of the vascular system. As described in the specification, the compounds of the present invention can be used in a variety of applications including treatment or diagnosis of any

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disease where aggregates of antibodies are produced and where immune complexes are produced by contact of antibody with intrinsic or extrinsic antigen. This is described to include vasculitities including but not limited to polyarteritis nodosa and systemic vasculitis. (Page 30, lines 4-18). Thus, the term vasculitities is used to describe disorders of immune production and response that occur in the vascular system. However, this does not reasonably include hypertension, cardiac failure and cardiac hypertrophy which are responsive to the compounds of Yanaka. Thus, the Applicants reiterate that there is no motivation for one of skill in the art to modify the compounds of Yanaka to arrive at the presently claimed compounds and, as described above, the compounds of Yanaka do not teach all of the limitations of the present claims and respectfully request that the rejection under 35 U.S.C. § 103(a) be withdrawn.

Based upon the foregoing, Applicants believe that all pending claims are in condition for allowance and such disposition is respectfully requested. In the event that a telephone conversation would further prosecution and/or expedite allowance, the Examiner is invited to contact the undersigned.

Respectfully submitted,

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